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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,869	06/12/2001	Kazuhiko Take	209334USOPCT	1165

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EXAMINER	
BERNHARDT, EMILY B	
ART UNIT	**PAPER NUMBER**
1624	5

DATE MAILED: 06/20/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/857,869	TAKE et al.
Examiner	**Art Unit**
Emily Bernhardt	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above, claim(s) 5 (in part) is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-10 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 & 4
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

In accord with 35 USC 121 and 372, applicants are advised that where more than one process of making is claimed along with compounds, the first recited process is considered to form part of the main invention. See 37 CFR 1.475(d). Thus only the first process in claim 5 along with remaining claims is being examined.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claims 2,3,7-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1.In claims 2 and 3 the provisos appear unnecessary since they appear in main claim 1. If applicants disagree they should point out how they further limit scope.

2.Claims 7, 9 and 10 do not further limit scope of claim 1 since intended uses in compound claims have no patentable weight.

3. Scope of "diseases" in 8 is indeterminate since the claim language may read on diseases not yet known to be affected by tachykinin receptors or in ways not yet understood as more testing and understanding of the biology of tachykinin receptors

(which includes many types) becomes available later in time. Defining a disease(s) by its (their) underlying cause renders the scope of intended uses indeterminate since the claim language may read on diseases not yet known to be caused by or affected by such action or in ways not yet understood. Additionally, determining whether a given disease responds or not to tachykinin antagonists involves much experimentation since a negative response from one patient does not mean the drug isnt useful as no drug has 100% effectiveness. Thus what "success rate" determines if a particular inhibitor is effective and how many patients (and dosage regimens) need to be tested? The test for determining compliance with 35 USC 112, par.two is whether applicants have clearly defined "their" invention and not what may be discovered by future research as this type of claim language clearly requires.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants provide no competent evidence that instantly disclosed test(s) on pp.24-25 are reasonably predictive of in vivo efficacy for treating as well as preventing all the uses described in the

specification which are embraced(but not limited to) in claim 8 . Such a list which includes notoriously difficult diseases to treat and prevent such as Alzheimer's, Huntington's Chorea,Down's Syndrome,etc.,etc. is simply an invitation to experiment. In re Kirk 153 USPQ 48. Note Ohnmacht, a recent publication, which while dealing with recent advances in the field of neurokinins does not evidence the scope of diseases being claimed herein. See Hoffman v. Klaus, 9 USPQ 2d 1657; Ex parte Powers 220 USPQ 924 regarding the standard of testing needed to show in vivo efficacy. Where the utility is unusual or difficult to treat or speculative, the examiner has authority to require evidence that tests relied on are reasonably predictive of in vivo efficacy by those skilled in the art. See for example, In re Ruskin 148 USPQ 221; Ex parte Jovanovics 211 USPQ 907. Note MPEP. 2164.05(a).

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 7, 9 an 10 are rejected under 35 U.S.C. 101 because

the claimed invention is directed to non-statutory subject matter. Claims drafted in terms of "use" have been held to be nonstatutory. Note Clinical Products v. Brenner 149 USPQ 475.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,6-10 are rejected under 35 U.S.C. 102(a) as being anticipated by Miyake (WO'954). The commonly assigned publication discloses some species within the instant scope as well as process of making recited herein. See starting material employed in example 6 and eg.36. Same activity as relied on herein is also taught in said reference.

Applicant cannot rely upon the earlier foreign priority paper to overcome this rejection because while present in the file and in English, the priority paper filed 12/14/98 is incomplete. Note every other page is missing.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miyake (WO'954). While final products such as in eg.3 do not anticipate the pyridyl species in claim 4 it is an obvious variant, since Miyake teaches not only methyl as substituents on 2-benzyl but also hydroxy. See p.15. Also, first process of claim 5 is taught as one of several processes for making Miyake's compounds of Formula I which generically include instant compounds. See Process 1 which is detailed on p.25 and employed in working examples such as 6 for making very similar compounds to that claimed herein. Thus it would have been obvious to one skilled in the art at the time the invention was made to also expect hydroxy,methyl substituted benzyl analogs of Miyake's compounds to also possess the same activity and to prepare such and analogous compounds also claimed by the process recited herein in view of the teachings outlined above.

Claims 1-3,5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuo (WO'597). Matsuo also teaches several compounds within the instant scope as well as employs instant process for making such. See egs. 51, 59 (33 and 5) and 60. Use as tachykinin antagonsist is also disclosed in said reference.

Claim4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuo (WO'597). While compounds such as egs. 81 and 87 in Matsuo do not anticipate the instant scope they are obvious variants since they only differ in nature of substituents on benzyl ring - dimethyl vs. instant OH,Me. However hydroxy in place of methyl is also taught as an alternate choice. See pages 12-13 in the WO publication. Thus it would have been obvious to one skilled in the art at the time the invention was made to replace dimethyl substituted species in Matsuo with other moieties expressly described including hydroxy and in so doing obtain one or more instantly claimed compounds for use as tachykinin antagonists in view of the teachings outlined above.

Claims 1,5-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Matsuo (EP'442). Matsuo also describes and prepares in the same manner as herein

an instant compound within the claims' scope for use as tachykinin antagonists. See eg.60(#7).

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-10 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No.6,087,357. Although the conflicting claims are not identical, they are not patentably distinct from each other because they embrace overlapping subject matter. Compare R and Y variables claimed with that embraced herein. US'357 corresponds to WO'597 applied above.

Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/899,942. Although the conflicting claims are not identical, they are not patentably distinct from each other because they embrace overlapping subject matter when R4 therein can be pyridyl-, pyrazolyl-, saturated heterocyclic alkyl. Said case is a refiled case of US'357 aplied above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/446145. Although the conflicting claims are not identical, they

are not patentably distinct from each other because they embrace overlapping subject matter to a large degree. Said application corresponds to WO'954 applied above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 6,087,357 and 09/899942 and 09/446145, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 CFR 1.78(c) and 35 U.S.C. 132 to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of

the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

E Bernhardt

EMILY BERNHARDT

PRIMARY EXAMINER

GROUP 1600